UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/417,175	10/11/99	HARPER	PC10139AMAG

EXAMINER	
N	

ART UNIT	PAPER NUMBER
1623	5

HM12/0213

GREGG C BENSON
PFIZER INC
EASTERN POINT ROAD
GROTON CT 06340

OH, T

DATE MAILED: 02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/417,175	Harper et al
Examiner	**Group Art Unit**
TAYLOR VICTOR OH	1623

☒ Responsive to communication(s) filed on *Dec 6, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-19* is/are pending in the applicat

Of the above, claim(s) *12-19* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a composition and sertraline compound, classified in class 564, subclass 308.

II. Claims 12-19, drawn to a method of using liquid concentrate of sertraline or method of treating diseases, classified in class 514 , subclass 255, 555, and 647.

2. The inventions are distinct, each from the other because of the following reasons: Inventions group I and group II are related as a compound and its composition and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said a compound and its composition and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Martha A. Gammill on 2/5/2001, a provisional election was made with traverse to prosecute the invention of group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Howard et al (U.S. 5,597,826).

Howard et al discloses a pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles, and preservatives (see col. 22, lines 51-56). This is identical to the claims.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howard et al (U.S. 5,597,826).

Howard et al discloses a pharmaceutical composition containing sertraline hydrochloride (see col. 20, line 31) with a dose from 0.1 mg to 200 mg (see col. 24, lines 7-8), suspending agents, non-aqueous vehicles such as ethyl alcohol, and preservatives (see col. 22, lines 51-56); in addition, oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Also, the reference indicates that pharmacologically acceptable anions include methanesulfonate (see col. 20, lines 60-61).

However, Howard et al differs from the instant invention in that 8 to 20 % ethanol is in glycerin, the flavoring agent is menthol, the preservative is butylhydroxytoluene, and each ml of

the concentrate contains 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin.

Johnson (EP 0768083 A2) discloses an oral pharmaceutical composition for treating myocardial infarction patients ; the composition contains sertraline or its pharmaceutically acceptable salt, flavoring agents, and diluents such as ethanol, propylene glycol, and glycerin (see from page 3 lines 58 to page 4, line 24).

Furthermore, Pollinger et al (U.S. 6,136,347) discloses pharmaceutical preparations for masking unpleasant substances in liquid form, which can contain a protective substance such as butylhydroxytoluene for an excipient media (see col. 9, lines 37-38).

Concerning the claimed range of ethanol in glycerin, the reference is silent. However, Johnson teaches the use of diluents such as ethanol and glycerin; furthermore, Pollinger et al does point out that liquid auxiliaries such as ethanol, propylene glycol, polyethylene glycol (see col. 8, lines 58-60) can be employed in an amount of from.5 to 40 % (see col. 6, lines 54-56). Therefore, the person having an ordinary skill in the art had desired to use an optimum range of ethanol in glycerin, it would have been obvious for the skillful artisan in the art to have obtained the claimed range of ethanol in glycerin by a routine experimentation on the Johnson's ethanol and glycerin with Pollinger et al's parameter so as to form a proper liquid dose.

In reference to the flavoring agent being menthol, the reference is silent. However, Howard et al does teach that oral pharmaceutical formulations can be flavored by means of various agents (see col. 23, lines 56-58). Furthermore, it is well-known in the art that menthol

has been used for masking unpleasant flavors. Therefore, the skillful artisan in the art had desired to develop a unique menthol taste in the oral pharmaceutical composition containing sertraline hydrochloride, it would have been obvious for the skillful artisan in the art to have selected the menthol flavor as the masking agent for the product.

With respect to each ml of the concentrate contained 151 mg of ethanol, 0.5 mg of menthol, 0.1 mg of butylhydroxytoluene, and 1011 mg of glycerin, the references are silent. However, the pharmaceutical oral composition can contain various excipients with varied concentrations so as to meet special needs for the patients' use. Therefore, the composition of various known excipients do not have any patentable weight in the instant invention in the absence of unexpected results.

Therefore, if the skillful artisan in the art had desired to develop a unique oral pharmaceutical composition containing sertraline hydrochloride, claimed various excipients with a menthol flavor, it would have been obvious for the skillful artisan in the art to have used Johnson's diluents such as ethanol and glycerin and Pollinger et al's butylhydroxytoluene preservative in Howard et al's oral pharmaceutical formulation so as to obtain an idealistic liquid product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Victor Oh whose telephone number is (703) 305-0809. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

2/8/2001

PAUL J. KILLOS
PRIMARY EXAMINER
1623